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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/554,933	08/21/00	KATO S	GIN-6713CPUS

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EXAMINER	
SEHARASEYON,J	
ART UNIT	PAPER NUMBER
1647	10

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

FILE COPY

Office Action Summary	Application No. 09/554,933	Applicant(s) KATO ET AL.	
	Examiner Jegatheesan Seharaseyon	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 July 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7-15* is/are pending in the application.

4a) Of the above claim(s) *12-15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *7* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. This office action is response to Applicant's election of Group I, claim 1, drawn to a protein of SEQ ID NO: 3. Applicant has elected to cancel the original claims in favor of the new claims 7-15. Claims 12-15 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group II, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 9 (6/29/01).

Specification

2. Applicants' figures have been approved by the draftsman.

3. The table on page 55 lacks a table number. Correction is required.

Claim Rejections - 35 USC § 101 and 112, first paragraph

3. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 7-11are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

The instant claims are directed to polypeptides, comprising SEQ ID Nos: 3 belonging to an allegedly human protein having transmembrane domain. These claims are drawn to an invention with no apparent or disclosed patentable utility. The instant application has provided a partial description of the isolated protein. However, the application does not disclose molecular weight or other physical properties of this protein. In addition, the instant application does not disclose the biological role of this protein or its significance.

It is clear from the instant specification that the claimed peptide is *homologous* (90%) to known serine proteases (page: 50, first paragraph). However, the homology of a peptide is not a reliable indicator for the functional characteristics (see Scott et al. 1999). There is little doubt that, after complete characterization, this protein will probably be found to have a patentable utility. This further characterization, however, is part of the act of invention and, until it has been undertaken, Applicants' claimed invention is incomplete.

The instant situation is directly analogous to that of which was addressed in *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966), in which a novel compound which was structurally analogous to other compounds which were known to possess anticancer activity was alleged to be potentially useful as an antitumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C. 101, which required that an invention must have either an immediate obvious or fully disclosed "real-world" utility. The court held that:

> "The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility," "[u]nless and until a process is refined and developed to this point - where specific benefit exists in currently available form - there is insufficient justification for permitting an applicant to engross what may prove to be a broad field," and "a patent is not a hunting license," "[i]t is not a reward for the search, but compensation for its successful conclusion."

The instant claims are drawn to peptides which have a yet undetermined function or biological significance. Applicants have disclosed that they are in possession of polypeptide SEQ ID NO: 3. However, there is no actual and specific significance which can be attributed to said polypeptides identified in the specification, except the prophetic

recitation of potential uses, which include the use in pharmaceuticals controlling the proliferation and the differentiation of cells (page: 50, lines 18-24). Also, using these proteins for the preparation of antibodies is not considered a specific use. For this reason, the instant invention is incomplete. In the absence of a knowledge or biological significance of this protein, there is no immediately obvious patentable use for it. Since the instant specification does not disclose a "real-world" use for said polypeptides, except the prophetic recitation of potential uses, which include possible biological, diagnostic and therapeutic uses. In addition, there are no working examples that demonstrate any specific utility. Thus, the claimed invention is incomplete and, therefore, does not meet the requirements of 35 U.S.C. 101 as being useful. Therefore, since the peptide of the invention is not supported by a specific and substantial asserted utility or a well established utility, then the composition comprising the polypeptide and a carrier also are not supported by a specific and substantial asserted utility or a well established utility.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7-11 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112, second paragraph

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8, 9 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5a. Claim 8 is rejected as vague and indefinite in the recitation of the phrase "fragment". It is unclear what fragment is encompassed in the instant claims. Therefore, the metes and bounds of the claim are unclear. Claim 11 is rejected insofar as it depends on claim 8.

5b. Claim 9 is rejected as vague and indefinite for reciting "allelic variant", because the term "allelic variant" is not defined in the specification. Therefore, the metes and bounds of the claim is unclear. This is because a variant may encompass a single amino acid change or several amino acid changes and it is unclear what "allelic variants" are encompassed in this claim.

5c. Claim 9 is also rejected as vague and indefinite for reciting the phrase "stringent conditions". Stringency is a relative term, and the art does not recognize a single set of conditions as "stringent". The specification also does not provide an unambiguous definition for the term (several conditions are described in page: 55-56). In the absence of a recitation of clear hybridization conditions, claim 9 fails to define the metes and bounds of the claim.

Claim Rejections - 35 USC § 112, first paragraph

6a. Claim 8-11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *This is a written description rejection.*

The specification discloses a polypeptide of SEQ ID NO: 3. This meets the written description and enablement provisions of 35 USC 112, first paragraph. However, the specification does not disclose any polypeptide consisting of a fragment of a polypeptide comprising the amino acid sequence of SEQ ID NO:3 or a polypeptide consisting of a naturally occurring allelic variant of a polypeptide comprising the amino acid sequence of SEQ ID NO:3 or a polypeptide which is at least 60% homologous to a polypeptide encoded by the amino acid sequence of SEQ ID NO: 3. The claims as written, however, encompass polypeptide sequences which were not originally contemplated and fail to meet the written description provision of 35 USC 112, first paragraph because the written description is not commensurate in scope with the recitation of claims 8-11. The specification does not provide written to support the genus encompassed by the instant claims.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (*See Vas-Cath* at page 1116).

With the exception of an isolated polypeptide of SEQ ID NO:3, the skilled artisan cannot envision all the detailed chemical structure of the claimed polypeptides, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The polypeptide itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016. One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481, 1483. In *Fiddes v. Baird*, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class.

Therefore, only an isolated polypeptide of SEQ ID NO: 3, but not the full breadth of the claims meets the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. As a result, it does not appear that the inventors were in possession of various polypeptide sequences set forth in claims 8-10.

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.) Applicants are directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday December 21, 1999.

6b. Claims 8-10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for protein encoded by SEQ ID NO:3 does not reasonably provide enablement for a polypeptide consisting of a fragment of a polypeptide comprising the amino acid sequence of SEQ ID NO:3 or a polypeptide consisting of a naturally occurring allelic variant of a polypeptide comprising the amino acid sequence of SEQ ID NO:3 or a polypeptide which is at least 60% homologous to a

polypeptide encoded by the amino acid sequence of SEQ ID NO: 3. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. See *In re Wands,* 858 F.2d at 737, 8 USPQ2d at 1404. The factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue" include, but are not limited to: (1) the breadth of the claims; (2) the nature of the invention; (3) the state of the prior art; (4) the level of one of ordinary skill; (5) the level of predictability in the art; (6) the amount of direction provided by the inventor; (7) the existence of working examples; and (8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The instant claims read on polypeptide consisting of a fragment of a polypeptide comprising the amino acid sequence of SEQ ID NO:3 or a polypeptide consisting of a naturally occurring allelic variant of a polypeptide comprising the amino acid sequence of SEQ ID NO:3 or a polypeptide which is at least 60% homologous to a polypeptide encoded by the amino acid sequence of SEQ ID NO: 3. However, other than polypeptide of SEQ ID NO:3, the specification as filed fails to disclose any other polypeptide sequences

Despite knowledge in the art for producing polypeptides that are fragments, allelic variants and homologues of a given polypeptide, the specification fails to provide any guidance regarding the changes/modifications contemplated and yet retain the function of the proteins claimed. Furthermore, detailed information regarding the structural and functional requirements of the disclosed protein is lacking. Although it is accepted that the amino acid sequence of a polypeptide determines its structural and functional properties, predicting a protein's structure and function from mere sequence data remains an elusive task. Therefore, predicting which fragments, allelic variants and homologues would retain the functions of the protein is well outside the realm of routine experimentation. Thus, undue amount of experimentation would be required to generate changes/modifications contemplated and yet retain the function of the proteins claimed.

Applicants have not taught how one of skill in the art would use the full scope of polypeptide sequences encompassed by the invention of claims 8-10. The specification as filed does not sufficiently teach one of skill in the art how to make and/or use the full scope of the claimed sequences. The amount of experimentation required to make and/or use the full scope of the claimed sequences would require trial and error experimentation to determine the functional sequences. Given the breadth of claims 8-10 in light of the unpredictability of the art as determined by the lack of working examples and shown by the prior at of record, the level of skill of the artisan, and the lack of guidance provided in the instant specification, it would require undue experimentation for one of ordinary skill in the art to make and use the claimed invention. Claim 11 is rejected insofar as it depends on claim 8.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 7-11 are rejected under 35 U.S.C. 102(e) as being anticipated by Sheppard (U.S. Patent No. 6,153,420).

The instant invention is directed to a human protein having transmembrane domains (SEQ ID NO: 3).

Sheppard teaches a serine protease polypeptides. The polypeptide sequence (SEQ ID NO: 18) described by Sheppard in U.S. Patent No. 6,153,420 (columns 41-44) has 100% identity over its entire length to SEQ ID NO: 3 of the instant invention. Therefore, the disclosure of Sheppard anticipates claims 7-11.

8. No claims are allowed.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon whose telephone number is 703-305-1112. The examiner can normally be reached on M-F: 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 703-308-4623. The fax phone numbers for

the organization where this application or proceeding is assigned are 703-308-0294 for regular communications and 703-308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

JS
August 7, 2001

Jeffrey Stucker

JEFFREY STUCKER
PRIMARY EXAMINER